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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,735

11/19/2003

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EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/717,735	Applicant(s) WAGSTROM ET AL.	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Status of the Claims

Claims 1-40 are currently pending.

Claims 41-81 were cancelled.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-38, drawn to an expression vector for a multimeric polypeptide anchored on the surface of a genetically replicable package, classified in class 436, subclass 512, for example.
 - II. Claims 39-40, drawn to a method for producing a multi-subunit protein, classified in class 435, subclass 7.2, for example.
2. The inventions are independent and/or distinct, each from the other because of the following reasons:
3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as hybridomas. In addition, the product as claimed

can be used in a materially different process of using that product such as producing bacteriophage.

4. Because these inventions are distinct for the reasons given above and:
 - a. have acquired a separate status in the art as shown by the different classification, and/or
 - b. divergent subject matter which would require different bibliographic and/or classification searches; and/or
 - c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election (Burdensome Search)

5. This application contains claims directed to the following patentably distinct species of the claimed inventions:

Group I is drawn to an expression vector for a multimeric polypeptide anchored on the surface of a genetically replicable package comprising the use of the following Markush species:

- a. expression vector [e.g. M13 (please refer to claims 19-20 and 25-26)]

Applicant must elect, for the purposes of search, a **single species** of expression vector.

- b. host [e.g. *E. coli* (please refer to claims 21-25 and 35)]

Applicant must elect, for the purposes of search, a **single species** of host.

c. first polypeptide segment [e.g. variable domain and constant domain of IgE light chain (please refer to claims 2-8 and 17)]

Applicant must elect, for the purposes of search, a **single species** of first polypeptide segment. Additionally, applicant must also state if a leader sequence will be present and elect a **single species** of leader sequence. As well, applicant must state the orientation of the polypeptide segment in relation to the other polypeptide segments. Moreover, applicant must indicate if a suppressable nonsense codon is present and, if so, must elect a **single species** of suppressable nonsense codon.

d. second polypeptide segment [e.g. SEQ ID NO. 1 (please refer to claims 8 and 15-16)]

Applicant must elect, for the purposes of search, a **single species** of second polypeptide segment. Additionally, applicant must state the orientation of the polypeptide segment in relation to the other polypeptide segments. Moreover, applicant must indicate if a suppressable nonsense codon is present and if so must elect a **single species** of suppressable nonsense codon.

e. third polypeptide segment [e.g. variable domain and C_H1 domain of IgE heavy chain (please refer to claims 2-9, 17-18, and 25)]

Applicant must elect, for the purposes of search, a **single species** of third polypeptide segment. Applicant must elect, for the purposes of search, a

single species of first polypeptide segment. Additionally, applicant must also state if a leader sequence will be present and elect a **single species** of leader sequence. As well, applicant must state the orientation of the polypeptide segment in relation to the other polypeptide segments. Moreover, applicant must indicate if a suppressable nonsense codon is present and if so must elect a **single species** of suppressable nonsense codon.

f. cleavable peptide sequence [e.g. disordered region cleavable by degP (please refer to claims 1, 9, 15-16, and 29-34)]

Applicant must elect, for the purposes of search, a **single species** of cleavable peptide sequence. Additionally, applicant must indicate which polypeptide segment will contain a cleavable peptide sequence.

g. proteolytic agent [e.g. degP (please refer to claims 10-14, 16, 27-28, 32, and 36-38)]

Applicant must elect, for the purposes of search, a **single species** of proteolytic agent. Additionally, applicant must indicate if the proteolytic agent is endogenous or exogenous. If exogenous, applicant must also indicate if the proteolytic agent is expressed in the same vector as the polypeptide segments or in a different vector. If expressed in a different vector, applicant must indicate a **single species** of vector. Moreover, applicant must indicate where the proteolytic agent will be localized (e.g. periplasm). Furthermore, applicant must indicate which polypeptide

segment will be cleaved by the proteolytic agent. Applicant may elect two distinct species of proteolytic agent if and only if each proteolytic agent will specifically cleave two different polypeptide segments. However, all of the previously mentioned requirements must be met for both proteolytic agents and each must be a **single species**.

h. anchoring peptide sequence [e.g. coat protein III of phage M13 (please refer to claims 1, 18, and 25)]

Applicant must elect, for the purposes of search, a **single species** of anchoring peptide sequence.

Group II is drawn to a method described as producing a multi-subunit protein comprising the use of the following Markush species:

i. host [e.g. *E. coli* (please refer to Specification page 23, line 6)]

Applicant must elect, for the purposes of search, a **single species** of host.

ii. expression vector [e.g. fd (please refer to Specification page 35, paragraph 00156, lines 1-4)]

Applicant must elect, for the purposes of search, a **single species** of expression vector.

iii. multi-subunit protein [e.g. ICAM-1 dimers (please refer to claim 40 and Specification page 31, paragraph 00142, lines 3-4)]

Applicant must elect, for the purposes of search, a **single species** of multi-subunit protein.

It would necessarily be unduly burdensome to search each of the above Markush members of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

Accordingly, applicant is required under 35 U.S.C. 121 **to elect a single disclosed species from each of the above items a-h if Group I is elected or from each of the items i-iii if Group II is elected. Markushes must be elected (for example: election of *E. coli*; fd; ICAM-1 dimers: i.e. one species from each of the Markushes for Group II)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 and 39 are generic.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

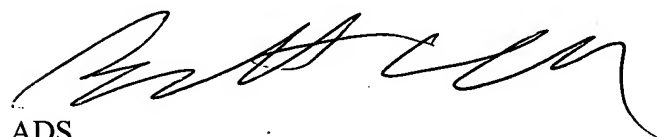
Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ADS
June 21, 2005

**BENNETT CELSA
PRIMARY EXAMINER**